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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,681	03/11/2004	David E. Adams	029036-0101	6251

7590 06/27/2005

James A. Wilke
Foley & Lardner LLP
777 East Wisconsin Avenue
Milwaukee, WI 53202-5306

EXAMINER	
BUNIN, ANDREW M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,681	ADAMS, DAVID E.	
	Examiner	Art Unit	
	Andrew M. Bunin	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *32-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to an apparatus that includes an enclosure for the inhalation tube, classified in class 128, subclass 200.14.

II. Claim 32-36, drawn to a method of using an apparatus that doesn't have an enclosure for the inhalation tube, classified in class 128, subclass 200.14.

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inhalation device of Group I must include an enclosure for holding the inhalation tube while the device used in the method of Group II doesn't require this constraint.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. James Wilke on June 16th, a provisional election was made with traverse to prosecute the invention of an apparatus with an enclosure for the inhalation tube, claims 1-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 32-36 are withdrawn from

further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "36 " and "37" have both been used to designate a medical reservoir. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 59. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As claimed, a human being would not properly limit the claims since it is included as nonstatutory subject matter that is naturally occurring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 8, 9, 11, 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Strupat et al (US 6358058). Strupat et al. discloses an inhalation

device to deliver a pre-selected dose of medication to a user, the inhalation device comprising an enclosure 202 having an inhalation tube 216, the inhalation tube 216 having an inlet end and an outlet end; a medication dispenser 214 coupled to the enclosure 202, with the dispenser in communication with the inhalation tube 216 as shown in Figures 2 and 3. Strupat et al. further disclose the device having a sensor 300 mounted in the enclosure with at least a portion extending into the inhalation tube, the sensor having a characteristic of bending in proportion to speed of gas flowing in a given direction within the inhalation tube (see Figure 6C). In addition, Strupat et al. disclose an electrical circuit 600 coupled to the sensor and medication dispenser, with the electrical circuit configured to trigger the medication dispenser, upon receipt of a signal from the sensor at a predetermined gas flow speed in the inhalation tube, wherein a dose of medication is expelled into the inhalation tube (see Figures 5 and 13). Strupat et al. continues to disclose the inhalation device of including a medication reservoir 204 coupled to the medication dispenser 214.

As for claim 5, Strupat et al. disclose the dispenser 214 positioned between the output end 224 of the inhalation tube and the sensor 308 as shown in Figure 3.

As for claim 8, the medication is disclosed as one of a powder and a liquid (column 5, lines 17-19) (column 13, lines 19-20). In addition, Strupat et al. also disclose an indicator coupled to the electrical circuit to indicate the medication has been delivered as shown in figures 16D-G and 17B-D.

As for claim 11, Strupat et al. disclose the gas being moved through the inhalation tube by a means for pumping gas 228. A pump is defined as "a device for

raising, compressing, or transferring fluid." (dictionary.com) Therefore, the valve system would be considered a means for pumping the gas by allowing the medicament to flush into inhalation tube. In addition, Applicant has stated that the gas may be delivered by a "pump, inhaler, air compressor, ventilator, respirator, aqua lung, or the like" (paragraph 16, lines 15-18). Therefore, Strupat et al.' device would meet this feature.

As for claims 13, 15, and 16, Strupat et al. disclose the electrical circuit, the sensor, and the medication dispenser are coupled to a direct current power source (column 11, lines 41-44). In addition, this device also includes a means for calibrating the electrical circuit as shown in Figure 11B. The inhalation device includes a communication module coupled to the electrical circuit for cataloging, transmitting, store and receiving data and instructions also shown in Figure 11 B.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strupat et al. in view of Wolf et al. (US 5505195) and further in view of Higashi (US 4696188). Strupat et al. has disclosed everything except the inhalation device including a thermal compensator. However, Wolf et al. has taught an inhalation device with thermistor sensors 425 mounted in the enclosure with at least a portion extending into

the inhalation tube and coupled to the electrical circuit to sense temperature of gas flowing in the inhalation tube. Wolf et al. doesn't teach the thermal compensator sensing the humidity of the gas. However, Higashi has taught a humidity sensor that also measures the ambient temperature (column 6, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply the thermal compensator taught by Higashi into the Strupat et al. inhalation device since powder inhalants need to be maintained at a specific range of temperature and humidity to be effective. Modifying the inhalation device with the sensor taught by Higashi is considered well known in the art at the time of the invention since Wolf et al has taught measuring the temperature of an inhalation device.

The references above disclose the claimed invention except for the thermal compensator being positioned between the output end of the inhalation tube and the sensor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the thermal compensator of Higashi at a position between the output end of the inhalation tube and the sensor, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strupat et al. Strupat et al. disclose everything except a disposable medication reservoir mounted in the enclosure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a disposable medication reservoir since it was

known in the art that medication reservoirs were disposable after each use. In addition, any type of medication vial has the ability to be disposed of after each use.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strupat et al. Strupat et al. has disclosed everything except the electrical circuit being mounted in the enclosure. However, the Applicant has stated, "the electrical circuit can be mounted in the enclosure or can be mounted external to the inhalation device" (paragraph 29, lines 10-12), therefore it has been shown that the instant invention would function as disclosed with the electrical circuit placed either within or outside of the enclosure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strupat et al. Strupat et al. has disclosed everything except the sensor responds only during intake of gas by the user of the inhalation device. However, the device of Strupat et al. is capable of responding only during the intake of gas by the user, therefore, it would be considered obvious to a person of ordinary skill in the art at the time of the invention to make this modification so that the sensor isn't affected by an exhaled airflow insignificant to the purpose of the inhaler.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strupat et al. Strupat et al. has disclosed that it was well known in the art at the time of the invention for a flow sensor to be a variable resistor (column 1-2, lines 61-67). Strupat et al. states that potentionmeters (variable resistor) were once used for measuring flow rate. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the Strupat et al. flow sensor with a variable resistor as taught by Strupat et al. in order to be more precise in measuring varying voltages.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. (US 5522378) in view of Higashi (US 4696188). Ritson et al. discloses an inhalation device to deliver a pre-selected dose of medication to a user, the inhalation device comprising an enclosure 10 having an inhalation tube 20, the inhalation tube 20 having an inlet end and an outlet end; a medication dispenser 32 coupled to the enclosure 10, with the dispenser in communication with the inhalation tube 20 as shown in Figure 3. Ritson et al. further disclose the device having a sensor 505 mounted in the enclosure with at least a portion extending into the inhalation tube, the sensor having a characteristic of bending in proportion to speed of gas flowing in a given direction within the inhalation tube (see Figures 3 and 18C). In addition, Ritson et al. disclose an electrical circuit 41b coupled to the sensor and medication dispenser, with the electrical circuit configured to trigger the medication dispenser, upon receipt of a signal from the sensor at a predetermined gas flow speed in the inhalation tube, wherein a dose of medication is expelled into the inhalation tube (see Figures 19A and 19B). Ritson et al. continues to disclose the inhalation device of including a medication reservoir 31 coupled to the medication dispenser 32. Ritson et al. has taught a means for measuring temperature with a flow sensor (column 7, lines 1-6). However, Ritson hasn't disclosed a thermal compensator sensing humidity and being mounted in the enclosure with at least a portion extending into the inhalation tube and coupled to the electrical circuit. Higashi has taught a humidity sensor that also measures the ambient temperature (column 6, lines 60-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply the thermal compensator taught by

Higashi into the Ritson et al. inhalation device since powder inhalants need to be maintained at a specific range of temperature and humidity to be effective.

Claims 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. Ritson et al. disclose the medication dispenser 32 is positioned between the output end of the inhalation tube and the sensor 550 as shown in Figure 3. In addition, Ritson et al. has disclosed the electrical circuit 41b as being mounted in the enclosure as shown in Figure 4. Ritson et al. further disclose the medication is one of a powder and a liquid (column 11, lines 36-38). In addition, the inhaler has an indicator (alarm and display) coupled to the electrical circuit to indicate that medication has been delivered (column 32, lines 1-12).

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. Ritson et al. disclose everything except a disposable medication reservoir mounted in the enclosure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a disposable medication reservoir since it was known in the art that medication reservoirs were disposable after each use. In addition, any type of medication vial has the ability to be disposed of after each use.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. Ritson et al. has disclosed everything except the sensor responds only during intake of gas by the user of the inhalation device. Ritson et al. has disclosed that inhalation is separately calibrated for flow rate in the Abstract. The device of Ritson et al. is capable of responding only during the intake of gas by the user; therefore, it would be considered obvious to a person of ordinary skill in the art at the time of the invention to

make this modification so that the sensor isn't affected by airflow insignificant to the purpose of the inhaler.

Claims 26-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritson et al. Ritson et al. disclose the gas being moved through the inhalation tube by a means for pumping gas 200. A pump is defined as "a device for raising, compressing, or transferring fluid." (dictionary.com) Therefore, the actuator mechanism would be considered a means for pumping the gas by allowing the medicament to flush into inhalation tube. In addition, Applicant has stated that the gas may be delivered by a "pump, inhaler, air compressor, ventilator, respirator, aqua lung, or the like" (paragraph 16, lines 15-18). Therefore, Ritson et al. device would meet this feature. Ritson et al. continues to disclose the sensor as a variable resistor (column 29, lines 33-41). The device of Ritson et al. has a direct current power source 60 and 61 coupled to the electrical circuit, sensor, and medication dispenser. Lastly, Ritson et al. inhalation device includes a means for calibrating the electrical circuit and include a communication module 50 coupled to the electrical circuit for cataloging, transmitting, store and receiving data and instructions.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 5826570, US 5753815, US 5469750, US 6202642, and US 6845770

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMB
6/23/05

Henry Bennett
Supervisory Patent Examiner
Group 3700